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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/054,552	01/21/2002	Torrance M. Nett	2730-97-CON	8297

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EXAMINER	
DESAI, ANAND U	

ART UNIT	PAPER NUMBER
1653	

DATE MAILED: 09/08/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/054,552	NETT ET AL.	
	Examiner	Art Unit	
	Anand U Desai, Ph.D.	1653	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *21 January 2002*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *9-22* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *9-22* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *20020121*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Priority

1. Applicant's claim for domestic priority under 35 U.S.C. 120 is acknowledged. The priority date is February 23, 1989.

Information Disclosure Statement

2. The information disclosure statement (IDS) submitted on January 21, 2002 has been considered by the examiner.

Specification

3. The disclosure is objected to because of the following informalities:

4. The lineage of applications is incorrectly identified. Applicant is referred to U.S. Patent 6,326,467 B1 related application section of the specification, which describes a different association with prior applications. For example, the priority claim of application 07/837,639 filed February 14, 1992 to application 07/314,653, filed on February 23, 1989, now abandoned is a continuation-in-part.

Appropriate correction is required.

Double Patenting

5. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970);and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

6. Claims 9-18, 21, and 22 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-3 of U.S. Patent No. 5,378,688. Although the conflicting claims are not identical, they are not patentably distinct from each other because the current application claims an undisclosed species encompassd by the genus claim of Nett et al. U.S. Patent 5,378,688. The current application claims a hormone/toxin conjugate having the general formula: pyroGlu-His-Trp-Ser-Tyr-X-Leu-Arg-Pro, where X is an amino acid selected from the group consisting of lysine, D-lysine, ornithine, D-ornithine, glutamic acid, D-glutamic acid, aspartic acid, D-aspartic acid, cysteine, D-cysteine, tyrosine, and D-tyrosine. Nett et al. U.S. Patent 5,378,688 claims a method for sterilizing an animal, by administering an effective amount of a conjugate compound comprised of a gonadotropin releasing hormone or an analog thereof conjugated to a toxin, wherein the conjugate compound is capable of crossing the cell membrane of a gonadotroph (see U.S. Patent '688, claims 1-3, current application, claims 9-18, 21, and 22). Nett et al. U.S. Patent 5,378,688 does not distinctly claim the species claimed in the current application SN 10/054,552, but it would have been obvious to a person having ordinary skill in the art to conjugate the disclosed species, which lacks a carboxy terminal glycine compared to a claimed species in U.S. Patent '688 with a toxin to sterilize an animal.

7. Claims 9-22 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-18 of Nett et al. U.S. Patent No. 5,488,036. Although the conflicting claims are not identical, they are not patentably distinct from each other because the current application claims an undisclosed species encompassd by the genus claim of Nett et al. U.S. Patent 5,488,036. The current application claims a hormone/toxin conjugate having the general formula : pyroGlu-His-Trp-Ser-Tyr-X-Leu-Arg-Pro, where X is an amino acid selected from the group consisting of lysine, D-lysine, ornithine, D-ornithine, glutamic acid, D-glutamic acid, aspartic acid, D-aspartic acid, cysteine, D-cysteine, tyrosine, and D-tyrosine. Nett et al. U.S. Patent No. 5,488,036 claims a method for sterilizing an animal, by administering an effective amount of a conjugate compound comprised of a gonadotropin releasing hormone or an analog thereof conjugated to a toxin, wherein the conjugate compound is capable of crossing the cell membrane of a gonadotroph (see U.S. Patent '036, claim 1). Nett et al. claim a method further comprising challenging an animal with GnRH at least about four weeks after administration of the conjugate, wherein the challenge does not induce substantial secretion of luteinizing hormone by the animal. Nett et al. also claims a method of administering a conjugate at least once over a time period such that the conjugate does not elicit a substantial production of antibodies against the conjugate (see U.S. Patent '036, claims 1-18, current application, claims 9-22). Nett et al. U.S. Patent 5,488,036 does not distinctly claim the species claimed in the current application SN 10/054,552, but it would have been obvious to a person having ordinary skill in the art to conjugate the disclosed species, which lacks a carboxy terminal glycine compared to a claimed species in U.S. Patent '036 with a toxin to sterilize an animal.

Claim Rejections - 35 USC § 112

8. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

9. Claims 9-22 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

10. In claims 9 and 21, "hormone/toxin conjugate" is indefinite. The phrase "a hormone conjugated with a toxin" is suggested.

11. Claim 9 and 22 recite "capable of" in several locations, which is indefinite in each instance; either it does or it doesn't do something. A positive recitation with active verbs is suggested.

12. In claim 9, what defines a "chemical toxin?" The metes and bounds are not clear.

13. In claim 13, the recombinantly produced protein "inhibits biosynthesis" of what?

14. In claim 21, what does it mean to "functionally inactivate cells?"

15. Claims 10-12, and 14-20 are rejected for depending on a rejected claim.

16. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

17. Claim 15 is rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter, which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had

possession of the claimed invention. The instant claim is directed to a single chain toxin selected from the group consisting of pokeweed antiviral protein, α-amanitin, gelonin ribosome inhibiting protein ("RIP"), barley RIP, wheat RIP, corn RIP, rye RIP, flax RIP, and modified forms thereof. It is not clear what modified forms thereof the inventor had possession of from the disclosure of the invention. The Court of Appeals for the Federal Circuit has recently held that a "written description of an invention involving a chemical genus, like a description of a chemical species, 'requires a precise definition, such as be structure, formula [or] chemical name,' of the claimed subject matter sufficient to distinguish it from other materials." *University of California v. Eli Lilly and Co.*, 1997 U.S. App. LEXIS 18221, at *23, quoting *Fiers v. Revel*, 25 USPQ2d 1601, 1606 (Fed. Cir. 1993) (bracketed material in original).

Just as the claims at issue in *UC v. Lilly* defined the invention by the function of the claimed DNA (encoding insulin), the instant claims define the claimed products only by their functional properties. The court held this sort of functional definition insufficient. "In claims involving chemical materials, generic formulae usually indicate with specificity what the generic claims encompass. One skilled in the art can distinguish such a formula from others and can identify many of the species that the claims encompass. Accordingly such a formula is normally an adequate description of the claimed genus. In claims to genetic material, however, a generic statement such as 'vertebrate insulin cDNA' or 'mammalian insulin cDNA,' without more, is not an adequate written description of the genus because it does not distinguish the genus from others, except by function. It does not specifically define any of the genes that fall within its definition. It does not define any structural features commonly possessed by members of the genus

that distinguish them from others. One skilled in the art therefore cannot, as one can do with a fully described genus, visualize or recognize the identity of the members of the genus. A definition by function, as we have previously indicated, does not suffice to define the genus because it is only an indication of what the gene does, rather than what it is." *UC v. Lilly*, at *24-*25, thus the above claim lacks adequate written description.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Anand U Desai, Ph.D. whose telephone number is (571) 272-0947. The examiner can normally be reached on Monday - Friday 9:00 a.m. - 5:30 p.m..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jon P. Weber can be reached on (517) 272-0925. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

August 30, 2004

Jon P. Weber, Ph.D.
Primary Examiner